

amendment or are traversed by argument below.

1. Election/Restriction

Claims 2, 4, and 14-21 have been canceled without prejudice as to further prosecution of the subject matter in future related applications.

2. Drawings

The Examiner objected to Figures 2-3 because the specification did not provide a description of the number values in figures. In addition, the Examiner pointed out that Figure 1 was incorrectly listed as Figure 3 on page 6 of the specification. The specification has been amended to overcome these objections.

3. Rejections of claims 1, 3, and 5-13 under 35 U.S.C. § 112, first paragraph

Claims 1, 3, and 5-13 stand rejected under 35 U.S.C. § 112, first paragraph, as not providing written description for "polypeptide sequences that comprise unknown and undescribed sequences, that are fused to unknown or undescribed heterologous polypeptide (i.e., as it relates to claim 6) or what constitutes allelic variants of the polypeptide of SEQ ID NO: 7 from rat or any different species (i.e., as it relates to claims 3 & 5)."

Claims 3 and 5 have been cancelled, thereby obviating the rejection as it relates to claims 3 and 5. Claims 6 and 8 have been amended to depend from claim 1 only. Therefore, since claims 6 and 8 no longer depend from claims 3 and 5, claims 6 and 8 are free from the rejection as it relates to claims 3 and 5. Claim 7 depends from claim 6; therefore, claim 7 is free from the rejection. Claim 9 depends from claim 8; thus, claim 9 is free from the rejection. Claim 11 has been amended to depend from claim 1, therefore claim 11 and the claims depending from claim 11 are also free from this rejection.

As the rejection relates to claim 6, Applicants contend that the specification contains a sufficient written description of the fusion polypeptides of the invention. Claim 1, as amended, is drawn to polypeptides consisting of SEQ ID NO: 7 (VGF-5). Claim 6 is drawn to a fusion polypeptide consisting

of a heterologous amino acid sequence and SEQ ID NO: 7. Fusion polypeptides are described in the specification on page 19, line 26 to page 21, line 10. Specifically, heterologous polypeptides that may be fused to VGF-5 are described in the specification. For example, at page 20, line 26 to page 20, line 7:

In addition, VGF polypeptides may be fused to a homologous polypeptide to form a homodimer or to a heterologous polypeptide to form a heterodimer. Heterologous peptides and polypeptides include, but are not limited to: an epitope to allow for the detection and/or isolation of a VGF fusion polypeptide; a transmembrane receptor protein or a portion thereof, such as an extracellular domain or a transmembrane and intracellular domain; a ligand or a portion thereof which binds to a transmembrane receptor protein; an enzyme or portion thereof which is catalytically active; a polypeptide or peptide which promotes oligomerization, such as a leucine zipper domain; a polypeptide or peptide which increases stability, such as an immunoglobulin constant region; and a polypeptide which has a therapeutic activity different from the VGF polypeptides of the present invention.

The specification at page 27, lines 21-23 refers to "homologous" as from the same species and/or strain as the host cell, and the term "heterologous" as from a species other than the host cell species or strain. Table 3 on page 21 provides examples of fusion proteins comprising regions of human IgG. Also, Example 1 of the specification describes the fusion of VGF polypeptides of the invention with Keyhole Limpet Hemocyanin (page 78, line 14). Thus, the specification provides a sufficient written description of fusion polypeptides consisting of a heterologous amino acid sequence and the polypeptide consisting of SEQ ID NO: 7, as encompassed by the claims (as it relates to claim 6 and the claims that depend from claim 6). Consequently, Applicants respectfully submit that the statutory requirements have been met and request that this ground of rejection be withdrawn.

Claims 1, 3, and 5-13 also stand rejected under 35 U.S.C. §112, first paragraph, as enabling only for "a polypeptide consisting of the sequence set forth in SEQ ID NO: 7 that increase body weight." Claims 3, 5, and 10 have been cancelled, thereby obviating this rejection as it relates to claims 3, 5, and 10. Claim 1 has been amended to recite "a polypeptide consisting of the amino acid sequence as set forth in SEQ ID NO: 7." Claims 6, 8, and 11 have been amended to depend only from claim 1. The pending claims as amended and the claims that depend from them are free from this rejection. Consequently, Applicants respectfully request that this ground of rejection be withdrawn.

4. Rejection of claims 3 and 5-13 under 35 U.S.C. § 112, second paragraph

Claims 3 and 5-13 stand rejected as indefinite for reciting “the activity of the polypeptide as set forth in SEQ ID NO: 7.” Claims 3, 5, and 10 have been cancelled, thereby obviating this rejection as it relates to claims 3, 5, and 10. Claims 6, 8, and 11 have been amended to depend on claim 1. Consequently, claims 6, 8, and 11, and the claims that depend from them, are free from this rejection. Thus, applicants respectfully request that this ground of rejection be withdrawn.

5. Rejections of claims 1, 3, 5-6, and 8-11 under 35 U.S.C. § 102

Claims 1, 3, 5-6, and 8-11 stand rejected as being anticipated by Salton *et al.* (1991). Claims 3, 5, and 10 have been cancelled, thereby obviating this rejection as it relates to claims 3, 5, and 10. Salton *et al.* teach the NGF33.1 nucleic acid and amino acid sequence, with the predicted amino acid sequence common to VGF and NGF33.1 underlined. A portion of the underlined amino acid sequence is identical to the sequence of SEQ ID NO: 7. Claim 6 has been amended to encompass fusion polypeptides consisting of SEQ ID NO: 7 fused to a heterologous amino acid sequence. The portion of the sequence taught by Salton *et al.* that corresponds to SEQ ID NO: 7 is not fused to a heterologous sequence. Rather, the portion is embedded in the native NGF33.1 sequence. Thus, Salton *et al.* do not anticipate claim 6. Claim 1 has been amended to recite “a polypeptide consisting of the amino acid sequence as set forth in SEQ ID NO: 7.” Since Salton *et al.* teach a sequence that comprises the amino acid sequence as set forth in SEQ ID NO: 7, Salton *et al.* do not anticipate claim 1. Consequently, reconsideration and withdrawal of this ground of rejection is therefore respectfully requested.

Claims 3, 5-6, and 8-11 stand rejected as being anticipated by Possenti *et al.* (1989). Claims 3, 5, and 10 have been cancelled, and claims 6, 8, and 11, have been amended to depend from claim 1, which is not anticipated by Possenti *et al.*, thereby obviating this rejection.

Claims 5-6 and 10-11 stand rejected as being anticipated by Canu *et al.* (1997). Claims 5 and 10 have been cancelled, and claims 6 and 11 have been amended to depend from claim 1, which is not anticipated by Canu *et al.*, thereby obviating this rejection.

CONCLUSION

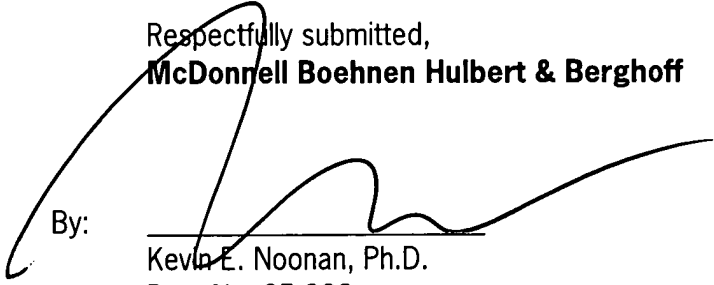
Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Hayes believes it to be helpful, he is invited to contact the undersigned representative by telephone at (312) 913-0001.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff

Date: July 26, 2002

By:



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AMENDMENTS TO THE SPECIFICATION

MARKED UP VERSION OF THE REPLACEMENT PARAGRAPHS UNDER 37 C.F.R. TECH CENTER 1600/29

1.121 (b)(1)(iii)

Page 6, lines 9-17:

Figure 1 illustrates the body weight of VGF knockout mice following administration of VGF-1a (SEQ ID NO: 2). The administration of VGF-1a was ceased at day 5 (as indicated by the arrow);~~illustrates the antibody titer levels of a rabbit injected with VGF-1 (SEQ ID NO:1);~~

Figure 2 illustrates the antibody titer levels of a rabbit injected with VGF-1 (SEQ ID NO:1), calculated at 1:100 to 2x serial dilution;~~illustrates the antibody titer levels of a rabbit injected with VGF-2 (SEQ ID NO:4);~~

Figure 3 illustrates the antibody titer levels of a rabbit injected with VGF-2 (SEQ ID NO:4), calculated at 1:100 to 2x serial dilution.~~illustrates the body weight of VGF knockout mice following administration of VGF-1a (SEQ ID NO: 2). The administration of VGF-1a was ceased at day 5 (as indicated by the arrow).~~

Page 80, line 27 to page 81, line 2:

Figure ~~13~~ illustrates the body weight of VGF knockout mice following administration of VGF-1a. Three of the four treated mice gained 10-15 percent in body weight. From this experiment, it was not possible to determine whether the increase in weight was a result of an increased uptake of food or water.

AMENDMENTS TO THE CLAIMS

MARKED UP VERSION OF AMENDED CLAIMS UNDER 37 C.F.R. 1.121(c)(1)(ii)

1. (Amended) An isolated polypeptide ~~consisting of~~comprising the amino acid sequence as set forth in ~~any of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, or SEQ ID NO: 10.~~

6. (Amended) A fusion polypeptide ~~comprising~~consisting of the polypeptide of ~~any of Claims 1, 2, 3, 4, or 5~~ fused to a heterologous amino acid sequence.

7. (Amended) The fusion polypeptide of Claim ~~6~~7 wherein the heterologous amino acid sequence is an IgG constant domain or fragment thereof.

8. (Amended) A composition comprising the polypeptide ~~of any of Claims 1, 2, 3, 4, or 5~~ and a pharmaceutically acceptable formulation agent.

11. (Amended) The polypeptide of Claim 10 which is covalently modified with a water-soluble polymer.